

1st MALARIA VACCINE SHIPMENTS: Frequently Asked Questions (FAQs)

Why are these shipments important?

These shipments represent the first time WHO-recommended malaria vaccine has been sent to countries outside of the pilot implementation countries, and they represent the final steps in preparation for scaled-up vaccination through routine immunisation programmes.

When will rollout begin?

These shipments represent one of the critical steps in preparation for broader rollout. First doses through routine immunisation will be administered beginning in Q1 2024.

What does country preparation involve?

In addition to the comprehensive preparations needed to introduce any new vaccine into routine immunisation programmes – such as training healthcare workers, investing in infrastructure, technical capacity, and vaccine storage, demand generation and community engagement, and sequencing and integrating rollout alongside the delivery of other interventions – the malaria vaccine requires careful planning to deliver a four-dose schedule. The malaria vaccine pilot programme provided crucial learnings on how to do this effectively.

How did we get here? Who played a role?

The first malaria vaccine recommended for use by WHO – RTS,S – was a breakthrough for science and public health, and decades in the making. Today's historic step to make malaria vaccine more broadly available represents decades of advocacy from those most impacted by malaria, coupled with years of research and development by GSK and Africa-based scientists, public-private investments, as well as collaboration among global health partners:

- In **2013**, the Gavi Board first considered an investment in malaria vaccination in lower-income countries, through Gavi's vaccine investment strategy.
- In **2016**, the Gavi Board approved funding for the Malaria Vaccine Implementation Programme, MVIP, to evaluate the public health use of the first malaria vaccine in routine immunisation programmes in selected (pilot) areas in Africa.
- Vaccine introductions in pilot areas were launched in **2019** in Ghana, Kenya and Malawi. The MVIP is coordinated by WHO working in collaboration with Ministries of Health, UNICEF, PATH, GSK and the funding partners Gavi, the Global Fund to Fight AIDS, Tuberculosis and Malaria and UNITAID.
- In **2019**, the Gavi Board approved a plan to de-risk investment to ensure doses of RTS,S were produced and available ahead of WHO recommendation and prequalification, leading to an agreement between Gavi, GSK and MedAccess in **2021**. This agreement helped fund the ongoing production of doses while evidence to support a broader policy decision was being collected.

- In October **2021**, WHO recommended the RTS,S vaccine to prevent malaria in children, and shortly thereafter, the Gavi Board approved Gavi support for a routine malaria vaccination programme in December 2021, which guaranteed the organization would provide financing for vaccine doses and introduction activities in Gavi-eligible countries. Gavi, WHO, UNICEF and a range of other immunization and malaria partners began working with interested countries to support evidence-based national decision-making on vaccine introduction, provide guidance, technical assistance and coordination.
- In June **2022**, Gavi opened the application window for countries who wished to rollout the vaccine through routine immunisation with Gavi support.
- In July **2022**, anticipating an initially constrained malaria vaccine supply, WHO published a Framework for the allocation of limited malaria vaccine supply that was developed with expert advice. The Framework provides guidance on the global allocation of RTS,S between countries, based on ethical principles and considerations, until supply constraints are fully resolved.
- In August **2022**, UNICEF signed a long-term agreement enabling procurement of RTS,S doses.
- Demand for malaria vaccines by countries in Africa has been unprecedented. At least 30 countries in Africa plan to introduce a malaria vaccine as part of their national malaria control plans. By April **2023**, a record number of first applications had been received and reviewed by Gavi's independent expert committee.
- In July **2023**, 18 million doses of RTS,S, the first malaria vaccine, were allocated to 12 African countries for 2023-2025. The allocations were determined through the application of the principles outlined in the Framework for allocation of limited malaria vaccine supply that prioritizes those doses to areas of highest need, where the risk of malaria illness and death among children are highest, until supply fully meets demand. The Framework implementation group that applied the framework principles included representatives of the Africa Centres for Disease Control and Prevention (Africa CDC), UNICEF, WHO and the Gavi Secretariat, as well as representatives of civil society and independent advisors. The group's recommendations were reviewed and endorsed by the Senior Leadership Endorsement Group of Gavi, WHO and UNICEF.
- In October **2023**, a second malaria vaccine, R21, was recommended by WHO. The R21 vaccine is currently undergoing the process of WHO prequalification, which is a prerequisite to international procurement of the vaccine in support of broader rollout.
- In the same month, UNICEF signed a long-term agreement to enable procurement of R21 doses post-WHO prequalification.
- In November 2023, first Gavi-funded doses arrived in countries and first shipments are now underway to non-pilot countries – signalling final steps towards broader vaccination against malaria on the African continent.

What is the malaria vaccine pilot programme?

- The Malaria Vaccine Implementation Programme, MVIP, was designed to evaluate the public health use of the RTS,S vaccine in Ghana, Kenya and Malawi. Initial findings from the pilot programme informed the first WHO recommendation for a malaria vaccine, RTS,S, in October 2021.
- Since 2019, over 2 million children at risk have been reached with the malaria vaccine across the 3 countries in Africa. The results of the evaluation of the MVIP after 4 years of vaccination show

that the malaria vaccine has reduced all-cause deaths among children age-eligible for vaccination by 13%, and hospital admissions with severe malaria by 22%.

- The MVIP pilot programme will be completed in December 2023.

When will a second malaria vaccine be approved and rolled out?

A second malaria vaccine, R21, manufactured by Serum Institute of India (SII), is in the process of WHO prequalification – which enables international procurement and delivery. WHO prequalification convenes experts to evaluate the safety, efficacy and quality of vaccines. It also involves testing the vaccines and inspection of the manufacturing facilities. A decision is expected in the coming months.

Once WHO prequalification is completed, it is expected that final steps to make doses available and ready for shipment will take a few months.

Are both malaria vaccines similar?

Both malaria vaccines are safe and effective. The two vaccines have not been tested in direct (head-to-head) comparison studies. However, given the similarity of the vaccines (in construct, target population and delivery), and available evidence, both malaria vaccines, when implemented broadly, are expected to have high public health impact.

WHO recommends both malaria vaccines should be provided in a schedule of 4 doses from around 5 months of age for the reduction of malaria disease and burden. The vaccine should be administered to children living in malaria endemic areas, prioritizing areas of moderate and high transmission.

How will countries decide which product to use?

Two malaria vaccines (RTS,S and R21) are recommended for use by WHO and available evidence indicates they are both safe and effective. The choice of product to be used in a country should be based on product characteristics and programmatic needs, vaccine supply availability and the likelihood of being able to scale up with a single product in the programme, and long-term affordability considerations.

Gavi, WHO, UNICEF and partners are currently in discussions with countries to understand the programmatic needs of each context, taking into the factors outlined below.

This means considerations for countries include the size of the target population for malaria vaccination compared to available volumes – and the ability to scale up without switching products. This means, for example, large countries are most likely to use R21, which is expected to be available in larger volumes, while smaller countries are likely to use RTS,S which is currently available in smaller volumes.

Additional considerations include affordability (which is relevant to countries in the later stages of transitioning out of Gavi support), vaccine presentation (R21 is fully liquid, while RTS,S does, although this is similar to other vaccines routinely administered such as measles/mumps/rubella vaccines), and R21 has slightly smaller cold chain storage implications, which may be relevant for countries that wish to rollout immediately but are concerned about current cold chain availability (before additional cold chain can be put into place).

How is malaria vaccination financed?

Malaria vaccination through routine programmes in lower-income countries is financed by Gavi, including the cost of doses and rollout. Per the Gavi model, countries also contribute a small portion of the cost of each dose, and this “co-financing” amount varies based on income level.

How much do malaria vaccines cost?

There is a difference between price of malaria vaccines and the cost countries pay.

The RTS,S vaccine costs a maximum of EUR 9.30 per dose (through 2025). The price reflects the fact that vaccine production is still scaling up and the supply is not yet in a steady state or benefitting from economies of scale. If cost of production decreases, this cost may reduce – with any refunds returned to countries and donors. It is also expected that the price of RTS,S will decrease once the technology transfer from GSK to BBIL is complete (expected currently sometime between 2028-2029). The R21 vaccine currently costs US\$ 3.90 per dose for a two-dose presentation, and this decrease in future years as additional demand materializes.

However, due to these vaccines being rolled out through Gavi support, the amount countries pay is different from the procurement price. In December 2022, the Gavi Board approved an exceptional co-financing approach that will be in place until 2027. Only countries at the final stages of transitioning out of Gavi support pay a direct proportion of price per dose (however, Gavi is working with this small subset of countries to ensure they can rollout with R21), while others pay a small amount per dose that is not product-specific (the lowest-income countries pay US\$ 0.20 per dose).

Are there enough malaria vaccine doses available?

18 million doses of RTS,S manufactured by GSK have been contracted by UNICEF Supply Division from now until 2025, while the manufacturer executes technology transfer to Bharat Biotech (BBIL) – and additional volumes are expected to be available in the coming years. If R21 receives WHO prequalification, this adds a second critical source of supply, and it is expected that supply of malaria vaccine will meet demand.